

Sample Table 1

Accrual from Cancer Treatment Protocols Conducted by Your Research Base Available for Use by CCOPs^{1, 2}

Directions: Column (3) Indicate pharmacologic phase as Phase I, II, III or Adjuvant.
Column (6) Indicate projected completion date based on current accrual rate, if applicable.

(1) Protocol Title	(2) NCI Protocol Number	(3) Pharmacologic Phase	(4) Disease Site	(5) Date Opened	(6) Projected Completion Date	(7) Number of Patients/Credits Entered ^{1,2}	
						7/1/03 thru 6/30/04 patients/credit	Total Since Opened patients/credits
						/	/
						/	/
						/	/
						/	/
						/	/
						/	/

Total: ____/____ ____/____

¹**Competing continuation** applicants should only count patients/credits entered through the CCOPs, not through Members/Affiliates.

² New applicants may report members= activity, since CCOPs were not available.

Sample Table 2a

Accrual from Cancer Prevention and Control Protocols Approved at your Research Base Available for Use by CCOPs, Members/Affiliates, and other Research Base Members/Affiliates (if for Intergroup Studies)^{1,2}

(List only protocols approved by the DCP Cancer Prevention and Control Protocol Review Committee³. In Column (5) indicate projected completion date based on current accrual rate, if applicable. Do not include protocols grandfathered in.)

(1) Protocol Title ⁵ (Precede with an * if Intergroup Protocol)	(2) NCI Protocol Number	(3) Target Sample Size	(4) Date Opened	(5) Projected Completion Date	(6) Credit Per Entry	(7) Number of Subjects/Credits Entered					
						CCOP ⁴		Member/Affiliate		Intergroup Studies ^{1, 2} Other RB Mem/Affil*	
						7/1/03 thru 6/30/04	Total* Since Opened	7/1/03 thru 6/30/04	Total* Since Opened	7/1/03 thru 6/30/04	Total* Since Opened
						(a) subjects/ credits	(b) subjects	(c) subjects /credits	(d) subjects	(e) subjects /credits	(f) subjects
						/		/		/	
						/		/		/	
						/		/		/	
						/		/		/	

Subj/Credits Subjects Subj/Credits Subjects Subj/Credits Subjects

Column Total for Table 2a: / / / /

Grand Total Credits 7/1/03-6/30/04: [Add credits in columns 7(a), 7(c), and 7(e)].

¹ Include only Intergroup studies where you have role as data coordinating center.

² Do not include Intergroup studies from other Research Bases.

³ Other than DCP-approved protocols may be listed if new applicant.

⁴ For DCP approved protocols with credit assigned to CCOPs only, enter the number of participants and zero (0) credits

⁵ Provide copies of any abstracts/manuscripts related to the protocols listed above.

Sample Table 2b

Accrual from Cancer Prevention and Control Protocols Sponsored by other CCOP Research Bases (Intergroup) for Use by Your Members/Affiliates.

(List only protocols approved by the DCP Cancer Prevention and Control Protocol Review Committee.)

In Column (5) indicate projected completion date based on current accrual rate, if applicable. Do not include protocols grandfathered in.)

(1) Protocol ¹ Title	(2) NCI Protocol Number	(3) Target Sample Size	(4) Date Opened	(5) Projected Completion Date	(6) Number of Subjects Entered Member/Affiliate	
					7/1/03 thru 6/30/04	Total Since Opened

¹ Provide copies of any abstracts/manuscripts related to the protocols listed above.

Participation in Cancer Prevention and Control Research Studies Sponsored by other Federally Funded Mechanisms (e.g., research project grant (R01), contract).

Directions: If applicable, provide the following information regarding the Research Base=s participation in cancer prevention and control research studies supported by other federally funded mechanisms.

- Column**
- (1) Indicate the Federally Funded Mechanism (e.g., Grant or Contract Number)
 - (2) Provide Title of the Study. Designate as either (C)= Currently Active; and/or (P) = Planned for Proposed Funding Period.
 - (3) Briefly describe primary involvement/participation in the research study
 - (4) Provide number of participants accrued for the period July 1, 2003 through June 30, 2004.
 - (5) Provide projected number of participants for proposed funding period.

(1) Federal Administrative & Funding Instrument e.g. R01CA12345, N01CN12345	(2) Title of the Research Study <u>Designate as either:</u> (C) Currently Active; and/or (P) Planned for Proposed Funding Period	(3) Primary Involvement in Research Study ** Indicate relationship of participants that apply: CCOP; cooperative group affiliate program; affiliate, member.	(4) Number of Participan ts accrued (7/03-6/04)	(5) Number of Proposed Participant Accruals
Example: R01CA11111	(C) Home Care Training for Breast Cancer Patients	Coordinate access to affiliated CCOPs to the research study	15	
Example: N01CN12345	(P) Phase II Trial DFMO in Cervix	RB member institution accrues to research study	N/A	20

**** Narrative explanation may be attached if needed to fully document your experience.**

Cancer Prevention and Control Concepts Approved by NCI for Protocol Development

(List only concepts approved by the DCP Cancer Prevention and Control Concept Review Committee since June 1, 2003.) ¹

Directions: Column (5) indicate projected completion date based on current accrual rate, if applicable.

(1) Concept Title	(2) NCI Concept Number	(3) Target Sample Size	(4) Projected Protocol Submission Date	(5) Projected Duration of Study	(6) Estimated Annual Accrual (Subjects)	
					CCOP	Member/ Affiliate

Total:

¹Other than DCP-approved protocols may be listed by new applicants.

(1) Concept Title	(2) Target Population	(3) Projected Concept Submission Date	(4) Projected Duration of Study	(5) Total Sample Size

CCOP Affiliations

Directions: Please include copies of signed Affiliation Agreements between the research base and each CCOP

(1) CCOP Name	(2) Full Name of Principal Investigator	(5) Projected Annual Accrual			
		Treatment		Cancer Prevention and Control	
		Patients	Credits	Subjects	Credits

Total: [TX : _____] [CC: _____]

Member/Affiliate Participation in NCI Approved Cancer Prevention and Control

(1) Member/Affiliate Name	(2) Full Name of Principal Investigator	(3) Location City, State, Zip	(4) Projected Annual Accrual	
			Protocols approved at your RB only	
			Subjects	Credits

Total: _____

“Prevention Members”

Please list the cooperative group members, affiliate programs and/or cancer center affiliates other than CCOPs that are included in the application as APrevention Members.®

Indicate with a (X) which of the following activities the “Prevention Member” contributes to in a significant way relative to the goals of the Research Base.

- (4) Substantial accrual to chemoprevention studies
- (5) Leadership in study implementation and management
- (6) Scientific leadership in the development of prevention clinical trials
- (7) Active membership in research base cancer prevention committees
- (8) Conduct of preclinical studies and/or Phase I and II clinical trials necessary for drug development
- (9) Conduct of correlative research, such as that related to mechanisms of action, biomarkers, molecular targets, etc.

Include a proposal for each APrevention Member® that describes how the member will contribute to the goals of the research base related to cancer prevention (See RFA Application Procedures, 2. Research Base Applicants, d. last paragraph). A separate budget must be provided for each APrevention member.®

(1) Member/Affiliate Name	(2) Full Name of Principal Investigator	(3) Location City, State, Zip	Areas of Significant Contribution					
			(4)	(5)	(6)	(7)	(8)	(9)

Reporting On-Site Auditing Activities for Cancer Prevention Trials, Large-scale e.g., (STAR), and Others, if applicable

For Large-scale Prevention Trials, e.g., the Study of Tamoxifen and Raloxifene (STAR), provide a list of ALL the participating institutions along with the audit schedule (MUST be provided) using the Table Format below.

For Other Prevention Trials that include participating Institutions other than Cooperative Group Treatment Trial institutions, provide a list of only these other institutions with their Audit Schedule using the Table Format below.

Instit. #	Name	Parent	Membership Date	Current Status (Active/Terminated)	Accrual _____*	Accrual _____*	Accrual _____*	Accrual Projected for upcoming year _____*	Date of last Audit	Date of Next proposed audit

*Fill in accrual blank with year (this should cover the preceding 36 months (e.g., 2001, 2002, 2003), if applicable.